



Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER: [REDACTED]
CASE TITLE: THERANOS, INC.
DOCUMENT NUMBER: 260282
PERSON INTERVIEWED: Dr. John Couvaras, IVF Phoenix
PLACE OF INTERVIEW: Telephonic
DATE OF INTERVIEW: 11/28/2017
TIME OF INTERVIEW: 0900 EST
INTERVIEWED BY: SA George Scavdis

OTHER PERSONS PRESENT: See below.

On 11/28/2017, the case agent telephonically interviewed Dr. John Couvaras, IVF Phoenix, regarding a patient of his (G [REDACTED] M [REDACTED]) who had blood tests performed by Theranos, Inc.

Dr. Couvaras explained that M [REDACTED] had a blood test with a QBhcg reading of 160 (this test was performed by Sonora Quest Laboratories on 09/03/2014). [Agent note: Human chorionic gonadotropin, hcg, is a hormone produced during pregnancy] He thought "it was a little early, but looking good" in terms of M [REDACTED] being pregnant. M [REDACTED] got a repeat blood test, this time through Theranos (this test was performed on 09/06/2014). Dr. Couvaras isn't sure why the second blood test was performed by Theranos and not Sonora Quest, but he thinks M [REDACTED] may have chosen Theranos for cost reasons. The data from the QBhcg test came back as "negative" for pregnancy. The data went from a reading of 160 to a reading of less than detectable, which Dr. Couvaras considered a "chemical loss." After the Theranos blood test which led Dr. Couvaras to conclude that M [REDACTED] was no longer pregnant, Dr. Couvaras stopped the current treatment protocol, and began recycling M [REDACTED] on medicines that a pregnant person shouldn't be taking. Subsequently, M [REDACTED] called the office and said she hadn't had her period. Dr. Couvaras told her to take another blood test, which she did on 09/22/2014. That test was also performed by Theranos, and the results for progesterone came back as "high" and the results for beta were 2150. When Dr. Couvaras saw those results, his initial thought was that M [REDACTED] might have an ectopic pregnancy. His notes for M [REDACTED] stated that they should have M [REDACTED] come in to the office because they were missing something. She came in to the office on 09/23/2014, and Dr. Couvaras performed an ultrasound on her. The ultrasound revealed that there was a sac in her uterus, and Dr. Couvaras determined that she was six weeks pregnant. The pregnancy they were seeing was in line with the pregnancy projected by the 09/03/2014 Sonora Quest Laboratory results. Dr. Couvaras explained that, with a pregnant patient, you would expect to see the QBhcg value double every two days. That holds true until the value levels off at somewhere between 5,000 and 12,000. If you take the original QBhcg 160 value measured by Sonora Quest and you double it every two days, you would have expected to see a value of between 5,000 and 12,000 at the time of the second Theranos blood test. The second Theranos blood test, though positive for pregnancy (2150), wasn't nearly as high as Dr. Couvaras would have expected it to be. Dr. Couvaras never saw M [REDACTED] after the 09/23/2014 office visit.

Typically, Dr. Couvaras sends patients to Sonora Quest for bloodwork. Theranos was radically cheaper, so if patients didn't have insurance, sometimes patients would ask if they could go to Theranos for their bloodwork.

The case agent noted that Dr. Couvaras placed M[REDACTED] on Acyclovir and Lovastatin after the first Theranos blood test that indicated a chemical loss, and he asked Dr. Couvaras what the potential patient impact was of placing a pregnant patient on those medications. Dr. Couvaras said that there is no patient impact when putting a pregnant patient on Acyclovir, but that Lovastatin is contraindicated for pregnant patients. Dr. Couvaras is not sure of the specific "anomaly" that can occur when placing a pregnant patient on Lovastatin, but it is a true contraindication.

Unless it's in the patient notes, Dr. Couvaras can't remember ever talking to anyone from Theranos. Other than M[REDACTED], he can't recall any other instances of patients getting inaccurate results from Theranos. He didn't ever recommend patients use Theranos, so he's not sure how often his patients used them; he just presented Theranos as an option to other laboratories.

SUBMITTED: Electronically submitted by GEORGESCAVDIS

GEORGE SCAVDIS, SPECIAL AGENT

DATE: 11/30/2017

APPROVED: Electronically approved by MARKMCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE

DATE: 12/01/2017

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cc: Prosecution

ATTACHMENTS: None